

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

<p>To:</p> <p>CERVELLI, ROBERT C/O ORIGIN BIOMEDICINALS INC. 5162 Duke Street Suite 520 Halifax, Nova Scotia Canada, B3J 1N7</p>	<p>PCT</p> <p>NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)</p> <p>(PCT Rule 71.1)</p>	
<p>Date of mailing (day/month/year) 20 December 2005 (20-12-2005)</p>		
<p>Applicant's or agent's file reference</p> <p>IMPORTANT NOTIFICATION</p>		
<p>International application No. PCT/CA2004/001659</p>	<p>International filing date (day/month/year) 21 September 2004 (21-09-2004)</p>	<p>Priority date (day/month/year) 23 September 2003 (23-09-2003)</p>
<p>Applicant ORIGIN BIOMEDICINALS INC. ET AL</p>		
<p>1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.</p> <p>2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.</p> <p>3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.</p>		
<p>4. REMINDER</p> <p>The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within <u>30 months from the priority date</u> (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).</p> <p>Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.</p> <p>For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the <i>PCT Applicant's Guide</i>.</p> <p>The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.</p>		
<p>Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476</p>	<p>Authorized officer</p> <p>Sophie Nadeau (819) 953-1736</p>	

BEST AVAILABLE COPY

PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
 (Chapter II of the Patent Cooperation Treaty)
 (PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/CA2004/001659	International filing date (day/month/year) 21 September 2004 (21-09-2004)	Priority date (day/month/year) 23 September 2003 (23-09-2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 7/48, A61K 9/06, A61K 35/78, A61P 17/00			
Applicant ORIGIN BIOMEDICINALS INC. ET AL			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No.I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 20 April 2005 (20-04-2005)	Date of completion of this report 20 December 2005 (20-12-2005)		
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Ingrid Elder (819) 934-2327		

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/001659

Box No. I Basis of the report

1. With regard to the language, this report is based on:

the international application in the language in which it was filed
 a translation of the international application into
 translation furnished for the purposes of:
 international search (Rules 12.3(a) and 23.1(b))
 publication of the international application (Rule 12.4(a))
 international preliminary examination (Rules 55.2(a) and/or 55.3(a))

, which is the language of a

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

 pages 1-9received by this Authority on
received by this Authority onas originally filed/furnished
13 January 2005 (13.01.05)

the claims:

 pages pages* pages* pages* 10-11as amended (together with any statement) under Article 19
received by this Authority on
received by this Authority onas originally filed/furnished
20 April 2005 (20.04.05)

the drawings:

 pages 1/1received by this Authority on
received by this Authority on

as originally filed/furnished

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages
 the claims, Nos. 11-17
 the drawings, sheets/figs
 the sequence listing (*specify*):
 any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages
 the claims, Nos.
 the drawings, sheets/figs
 the sequence listing (*specify*):
 any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/001659

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO
Inventive step (IS)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO
Industrial applicability (IA)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: US 6 150 422
 D2: EP 0 755 673
 D3: CA 2 353 071
 D4: US 5 665 367
 D5: CA 2 215 210
 D6: CA 2 221 236

Novelty

D1 discloses a stable gelled composition in the form of a cream, an ointment or a paste, wherein said composition contains at least one lipophilic polyphenol active agent sensitive to oxygen and/or to water, such as flavonoids; a gelling agent, such as a gum; and a solvent, such as vegetable oils. D1 also discloses that the oily gel comprising the lipophilic agent is stable for prolonged storage use.

D2 discloses a stable topical application containing at least one water-sensitive active agent, such as green tea extract; a polyol, such as glycerol or glycols; and a vegetable oil, such as jojoba oil. D2 also discloses that the polyol in combination with the structuring agent (aka oil) prevents the degradation of the water-sensitive actives.

D3 discloses a topical composition comprising an active agent, such as dithranol; an oil body from plant cells, such as coconut oil and jojoba oil; and a gelling agent, such as cellulose and gums (page 16, lines7-13).

D4 discloses a skin conditioning composition comprising a flavonoid, a retinol and a cosmetically acceptable vehicle. Example 10 discloses a non-aqueous skin care composition comprising a gum and herbal oils.

D5 and D6 disclose the incorporation of polyphenol extractions from tea (*Camellia sinensis*) and green tea into topical compositions.

The subject-matter of the Application is novel over D1-D6 in that the an adsorbent binding carrier to which a polyphenol is adsorbed is not disclosed in any of D1-D6.

Claims 1-11 are considered to be novel and therefore comply with Article 33(2) of the PCT.

(See Supplemental Box)

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/001659

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Inventive Step

The problem underlying the invention is to devise a means by which polyphenols can be evenly disbursed in anhydrous topical mixtures in order to provide polyphenol stability while providing suitable commercial appeal to a topical product and which will not inhibit the ability of the polyphenols to be released on and into the aqueous environment of the skin when topically applied.

This problem has been solved by the use of an inert adsorbent binding carrier and can be seen from the test results on pages 7-8 of the present Application.

This solution is considered surprising in light of D1-D6, which gave no indication as to how the improved properties were to be achieved, and so an inventive step can be acknowledged.

Claims 1-11 therefore comply with Article 33(3) of the PCT.

Industrial Applicability

The subject matter of claims 1-11 is considered to be industrially applicable and complies with Article 33(4) of the PCT since an anhydrous topical composition which evenly disburses polyphenols through the use of an inert adsorbent binding carrier is disclosed.

BEST AVAILABLE COPY